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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/220,920 | 12/24/98 | MILBRANDT | J 6029-7996 |

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EXAMINER

MURPHY, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1646

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DATE MAILED:

11/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/220,920

Applicant(s)

MILBRANDT ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,11,12,15-27 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 1,11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,15-27 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. Claims 12, 15, 16, 21, 23, 25, 26, 27 were amended and new claim 39 was added in Paper No. 11, 8/21/2000.
2. Claims 12, 15-27 and 39 are under consideration.

Response to Amendment

3. The objection to the Specification for the use of the word "Novel" in the title, as set forth in Paper No. 8, 5/18/2000, has been withdrawn based on Applicant's amendment.
4. The Information Disclosure Statement submitted in Paper No. 10, 8/21/2000, has been considered.
5. The rejection of claim 21 in Paper No. 8, 5/18/2000, under 35 USC § 112, first paragraph, for lack of written description due to a missing ATCC Deposit number has been obviated by Applicant's amendment, and is thus withdrawn.
6. The rejection of claims 12 and 15-27 in Paper No. 8, 5/18/2000, under 35 USC § 112, first paragraph for scope of enablement of "all" pan-growth factor proteins, has been obviated by Applicant's amendment, and is thus withdrawn.
7. The rejection of claims 15-16, 19-24 and 26 in Paper No. 8, 5/18/2000, under 35 USC § 112, first paragraph for scope of enablement of a "complement" of a nucleic acid has been obviated by Applicant's amendment, and is thus withdrawn.

8. The rejection of claim 23 in Paper No. 8, 5/18/2000, under 35 USC § 112, second paragraph as being indefinite has been obviated by Applicant's amendment, and is thus withdrawn.

9. The rejection of claim 26 in Paper No. 8, 5/18/2000, under 35 USC § 112, second paragraph as being indefinite has been obviated by Applicant's amendment, and is thus withdrawn.

Response to Arguments

10. Applicant's Arguments set forth in Paper No. 11, 8/21/2000 have been fully considered, but were deemed persuasive in part. Issues remaining, and new issues are discussed, below.

11. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

12. The rejection of claims 17-18 in Paper No. 8, 5/18/2000, under 35 USC § 112, first paragraph for scope of enablement of a "complement" of a nucleic acid has been maintained for reasons of record set forth in that Action.

13. The rejection of claims 12 and 25 in Paper No. 8, 5/18/2000, under 35 USC § 112, second paragraph as being indefinite as to which fragment Applicant is claiming has been maintained for reasons of record set forth in that Action.

14. The rejection of claim 16-18 in Paper No. 8, 5/18/2000, under 35 USC § 112, second paragraph as being indefinite for the language "specifically hybridizes" has been maintained for reasons of record set forth in that Action.

15. The rejection of claims 12, 15-16, 19-27 and new claim 39 under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained for reasons of record set forth in Paper No. 8, 5/18/2000. Specifically, claims 12, 15, 25 and 27, and claims dependent therefrom, are drawn to conservatively substituted variants of the sequences listed in the claims. Polynucleotide sequences are claimed which encode conservatively substituted variants of artemin polypeptide, however, in *University of California v. Eli Lilly*, 119 F.3d 1568, 43 USPQ2d at 1406. the Court decided that a definition by function alone "does not suffice" to sufficiently describe a nucleic acid sequence "because it is only an indication of what the gene does, rather than what it is." Further, "it is only a definition of a useful result rather than a definition of what achieves that result...The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention".

Furthermore, in *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016 at 1022 it was held that "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for

obtaining it, conception has not been achieved until reduction to practice has occurred, i.e. until after the gene has been isolated". Applicant has not set forth within the claim the detailed constitution of the nucleic acid encoding conservatively substituted variants of artemin polypeptide, and thus does not satisfy the written description requirement.

16. The rejection of claims 12 and 15-16 in Paper No. 8, 5/18/2000, under 35 USC § 102(a) as being anticipated by Waterston et al. (1998) has been maintained for reasons of record set forth in that Action.

17. The rejection of claims 19 and 20 in Paper No. 8, 5/18/2000, under 35 USC § 103(a) as being unpatentable over Waterston et al. (1998) has been maintained for reasons of record set forth in that Action.

Claim Rejections - 35 USC § 112 second paragraph

18. Claims 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claim 12 and 15 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Conclusion

19. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

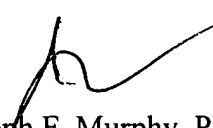
Art Unit: 1646

Advisory Information

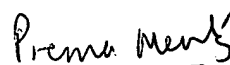
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
October 26, 2000


PREMA MERTZ
PRIMARY EXAMINER